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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

CROW, ROBERT THOMAS

ART UNIT PAPER NUMBER

1634

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/750,315 | Applicant(s) BERLIN ET AL. | |
| | Examiner Robert T. Crow | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 24-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner for this application has changed. Please address all future correspondence to Robert T. Crow, Art Unit 1634, telephone number (571)-272-1113.

Election/Restrictions

Applicant's election of Group II in the reply filed on 6 February 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-17 and 24-35 are therefore withdrawn. Claims 18-23 are currently under prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 23 is indefinite in the recitation "or aluminum mesh inside the channel" in lines 1-2 of the claim. It is unclear if the term "mesh inside the channel" only modifies "aluminum" or all of the metals listed in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Davis (U.S. Patent Application Publication No. US 2002/0102595, published 1 August 2002).

Regarding claim 18, Davis teaches an apparatus (e.g., a system for optical detection; claim 15) comprising a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface (e.g., an immobilized primer nucleic acid complex; claim 15), a channel in fluid communication with the reaction chamber (Figure 1), and a Raman detection unit operably coupled to the channel (e.g., the optical detection device [#13] of Figure 1 and claim 15, wherein Raman scattering is detected; paragraph 0054).

Regarding claim 19, Davis teaches the apparatus of claim 18, wherein the Raman detection unit is capable of detecting at least one nucleotide at the single molecule level (e.g., the device detects the optical properties of single molecules paragraph 0035).

Regarding claim 20, Davis teaches the apparatus of claim 18. The courts have held that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, “[A]pparatus claims cover what a device *is*, not what a device *does*.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 20 (e.g., measuring concentration of nucleotides) fail to define additional structural elements to the device of claim 18. Because Davis teaches the structural elements of claim 18, Davis also anticipates claim 20. See MPEP § 2114.

2. Claims 18-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Su et al (U.S. Patent Application Publication No. US2003/0186240 A1, published 2 October 2003).

A. The applied reference has common inventors and a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention

disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

B. Regarding claim 18, Su et al teach an apparatus (Abstract, line 1) comprising a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface, a channel in fluid communication with the reaction chamber, and a Raman detection unit operable coupled to the channel (page 11, claims 24-30 and Figures 1-3).

Regarding claim 19, Su et al teach the apparatus of claim 18, wherein the Raman detection unit is capable of detecting at least one nucleotide at the single molecule level (paragraph 0101).

Regarding claim 20, as stated above, the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Because Su et al teach the structural elements of claim 18, claim 20 is also anticipated by Su et al.

Regarding claim 21, Su et al teach the apparatus of claim 18 further comprising metal nanoparticles in the channel (paragraph 0017).

Regarding claim 22, Su et al teach the apparatus of claim 18, wherein the channel diameter is between about 100 and 200 micrometers (i.e., microns, μm) in diameter (paragraph 0092).

Regarding claim 23, Su et al teach the apparatus of claim 18 further comprising an aluminum mesh inside the channel (paragraph 0070).

3. Claims 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Shipwash (U.S. Patent Application Publication No. US 2002/0058273 A1, published 16 May 2002).

Regarding claim 18, Shipwash teaches an apparatus (e.g., an integrated microsystem using Raman spectroscopy; paragraph 0174) comprising a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface (paragraph 0043), a channel in fluid communication with the reaction chamber (Figure 11), and a Raman detection unit operably coupled to the channel (Figure 11, wherein the detector is a spectrophotometer [paragraph 0224] and Raman Spectroscopy is used; paragraph 0174).

Regarding claim 19, Shipwash teaches the apparatus of claim 18, wherein the Raman detection unit is capable of detecting at least one nucleotide at the single molecule level (e.g., the system employs detection is at the single molecule level; paragraph 0168).

Regarding claim 20, Shipwash teaches the apparatus of claim 18, wherein the concentrations of nucleotides are measured by Raman spectroscopy as they flow through the channel (e.g., the system detects concentration [paragraph 0170] and uses Raman spectroscopy; paragraph 0174). In addition, as stated above, the courts have held that “while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Because Shipwash teach the structural elements of claim 18, Shipwash also anticipates claim 20.

Regarding claim 21, Shipwash teaches the apparatus of claim 18 further comprising metal nanoparticles in the channel (e.g., nucleic acids are on particles are in channels; paragraph 0043).

Regarding claim 22, Shipwash teaches the apparatus of claim 18, wherein the channel diameter is between about 100 and about 200 micrometers (i.e., microns, μm) in diameter (paragraph 0210).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash (U.S. Patent Application Publication No. US 2002/0058273 A1, published 16 May 2002) in view of Anderson et al (U.S. Patent No. 6,168,948 B1, issued 2 January 2001).

Regarding claim 23, Shipwash teaches an apparatus (e.g., an integrated microsystem using Raman spectroscopy; paragraph 0174) comprising a reaction chamber containing a single template nucleic acid molecule attached to an immobilization surface (paragraph 0043), a channel in fluid communication with the reaction chamber (Figure 11), and a Raman detection unit operably coupled to the channel (Figure 11, wherein the detector is a spectrophotometer [paragraph 0224] and Raman Spectroscopy is used [paragraph 0174]; i.e., Shipwash teaches the apparatus of claim 18). While Shipwash also teaches a device further comprising a mesh (e.g., filter

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and grids on the device; paragraphs 0167 and 0270), Shipwash is silent with respect to the materials used for the mesh.

However, Anderson et al teach a miniaturized integrated nucleic acid diagnostic device comprising nucleic acid binding sites (Abstract) and a platinum screen with the added advantage that the platinum screen allows reproducible electrochemical functions (column 43, lines 7-12).

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was claimed to have modified the apparatus of Shipwash with the platinum screen (e.g., mesh) of Anderson et al with a reasonable expectation of success. The ordinary artisan would have been motivated to make such a modification because the modification would have resulted in allowing reproducible electrochemical functions as explicitly taught by Anderson et al (column 43, lines 7-12).

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 18-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-30 of copending Application No. 11/329,693. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising a reaction chamber, channels in fluidic communication with chambers, nanoparticles, and Raman detection of single nucleotide molecules, and differ only in the arrangement of the limitations within the sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 18, 20, 22, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 6, 7, 8, 10, 11, 13, and 15 of copending Application No. 11/255,386. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising a reaction chamber, channels in fluidic communication with chambers, nanoparticles, and Raman detection. While the claims of the '386 application include the limitation of an excitation source, the open language of the instant claims allows for this additional component of the '386 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 18-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 24-27 of copending Application No. 11/235,796. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising a reaction chamber, channels in fluidic communication with chambers, nanoparticles, and Raman detection or single nucleotide molecules. While the claims of the '796 application are drawn to an apparatus with a second channel and a flow through cell, the open language of the instant claims allows for the additional components of the '796 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 18, 20, 22, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 11, and 15 of copending Application No. 10/886,400. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising a reaction chamber, channels in fluidic communication with chambers, nanoparticles, and Raman detection. While the claims of the '400 application include the limitations of an excitation source as well as reagents

and nucleotide precursors, the open language of the instant claims allows for the additional components of the '400 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 18, 20, 22, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 11, 15, and 18 of copending Application No. 10/886,094. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising a reaction chamber, channels in fluidic communication with chambers, nanoparticles, and Raman detection. While the claims of the '094 application include the limitations of an excitation source as well as reagents and nucleotide precursors and the instant claims are drawn to a fluidic channel, the open language of the both sets of claims allows for the additional components of the each of the applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 18-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 27-30 of copending Application No. 10/660,902. Although the conflicting claims are not

identical, they are not patentably distinct from each other because both sets of claims are drawn to an apparatus comprising a reaction chamber, channels in fluidic communication with chambers, nanoparticles, and Raman detection or single nucleotide molecules. While the claims of the '902 application are drawn to an apparatus with a flow through cell, the instant claims interpreted such that the reaction chamber is the flow through cell of the '902 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 18 and 20-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 5-7 and 10-13 of U.S. Patent No. 6,982,165. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to reactions chambers with immobilized nucleic acids, Raman detectors, nanoparticles, metal mesh, and detection of single nucleotides. While the claims of the '165 patent include limitations of liquid in the flow path and the instant claims include structural limitations on the channels, the open language of the claims allows for the additional components of each of the sets of claims.

Conclusion

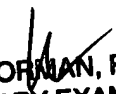
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert T. Crow
Examiner
Art Unit 1634



BJ FORMAN, PH.D.
PRIMARY EXAMINER